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REMARKS

Favorable consideration and allowance of the present application are respectfully requested.

Currently, claims 1-8 and 10-26, including independent claims 1, 13, and 20, are pending in the present application. Independent claim 1, for instance, is directed to a gastrostomy feeding device comprising an elongated feeding tube and an anchoring means mounted on the feeding tube to retain the feeding tube within the stomach. The anchoring means has at least one internal retaining member comprised of a modified silicone elastomer. More particularly, claim 1 requires that the modified silicone elastomer be a phenyl-modified silicone, a fluoro-modified silicone, or a combination thereof. It has been discovered that modified silicone elastomers as required in the claims can provide improved resistance to acidic and enzymatic degradation when the feeding device is implanted into the stomach of a patient.

In the Office Action, independent claims 1, 13 and 20 were rejected under 35 U.S.C. §103 as being obvious over U.S. Patent No. 4,834,721 to Onohara, et al. in view of U.S. Patent No. 4,198,983 to Becker, et al. Onohara, et al. is directed to a composite-shaped article made from a thermoplastic resin and silicone rubber. (Col 3, ll. 6-16). As opposed to the currently pending claims and as conceded in the Office Action, Onohara, et al. fails to disclose an internal retaining member comprised of a modified silicone elastomer selected from the group consisting of a phenyl-modified silicone and/or a fluoro-modified silicone.

In this regard, Onohara, et al. was combined with Becker, et al. Becker, et al. discloses a catheter shaft consisting essentially of from 40-70% by weight of an elastic composition which comprises:

> from 50 to 99.5% by weight of a block copolymer having thermoplastic rubber characteristics with a central, rubbery polyolefin block and terminal blocks of a polystyrene. The block copolymer preferably exhibits a Brookfield viscosity at 25°C. at 10 to 2000 cps., when measured using a 10 percent by weight solids solution in toluene. The composition also may contain up to 45 percent by weight of polypropylene, and from 0.5 to 10 percent by weight of a cross-linked silicone elastomer, preferably of the type described below, and preferably no more than 5 percent.

As stated in Col. 5 of Becker, et al., addition of the silicone provides increased slippery characteristics. As opposed to the currently pending claims, however, Becker, et al. only teaches using the silicone to form the catheter shaft and teaches using other materials in order to form a balloon retaining member.

Nonetheless, in the Office Action, the Examiner asserted that Onohara, et al. discloses that a catheter tube and balloon may each be made of the same material due to the following passage in Onohara, et al.:

> there can be provided a catheter tube with a balloon wherein the catheter tube and the balloon are each made of a same or different thermoplastic resin or silicon rubber and, at the balloon-fixing portion of the catheter tube, the catheter tube and the balloon are bonded strongly with an addition polymerization type silicone composition of the present invention. This catheter tube with a balloon enables wide and flexible selection for material combination of tube main body and balloon. (Col. 9, lines 12-18).

Based on the above passage, it was asserted that the siloxane disclosed in Becker, et al. may be used to form a catheter tube and balloon since Onohara teaches that a catheter shaft and balloon may be each made of the same material.

In response, Applicants emphasize that the teachings of the references must be viewed in their entirety, i.e., as a whole, to sustain a *prima facie* case of obviousness. Further, there must be some motivation, suggestion or incentive to combine the references as asserted. In this case, there must be some motivation, suggestion or incentive to form an internal retaining member from a phenyl-modified silicone or from a fluoro-modified silicone. Applicants assert that neither reference provides the necessary motivation, suggestion or incentive to render the presently pending claims obvious.

For instance, Onohara, et al. merely states that a catheter tube and a balloon may be made from the same or different thermoplastic resin or silicone rubber. Nowhere does Onohara, et al. even disclose a phenyl-modified silicone or a fluoro-modified silicone, let alone any type of teaching to use one of these materials in forming a balloon on a catheter.

Becker, on the other hand, actually teaches away from forming a retaining member or balloon from a phenyl-modified silicone or a fluoro-modified silicone. In particular, Becker, et al. states that the shaft of a catheter can be made from a thermoplastic material containing as one ingredient a cross-linked organic silicone elastomer in order to increase the slipperiness of the shaft. With respect to the balloon retaining member, on the other hand, Becker teaches forming the balloon from a mixture of block copolymers in a mineral oil. Thus, not only does Becker fail to provide

any motivation, suggestion or incentive to construct a balloon from a phenyl-modified silicone or from a fluoro-modified silicone, Becker in fact teaches forming the balloon from other types of materials. As such, it is believed that the claims patentably define over Onohara, et al. either alone or in combination with Becker, et al.

Further, the Examiner's attention is also directed to the examples contained in the present application. In the examples, a retaining member made from the materials of the present invention are compared with retaining members formed from a conventional organopolysiloxane. The examples show that the silicone elastomers of the present invention provide stronger acid resistance compared to the conventional material. The physical properties were also shown to be improved. These advantages and benefits are also not recognized or disclosed in either Onohara, et al. or Becker, et al.

In the Office Action, the Examiner also asserted that Applicants have not clearly defined what comprises the internal retaining member and that part of the catheter disclosed by Onohara, et al. may be considered to be part of the internal retaining member. In response, Applicants submit that the claims call for an elongated feeding tube and an internal retaining member. The internal retaining member is clearly a separate element from the elongated feeding tube. As such, Applicants believe that a catheter shaft as disclosed in Becker, et al. cannot somehow be interpreted to include a retaining member as asserted.

In the Office Action, claim 1 was also rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,439,443 to Miyata, et al. in view of U.S. Patent No. 4,604,412 to Joh, et al. Miyata, et al. discloses a balloon catheter for use in an

intraaortic balloon pumping in the treatment for heart failure caused by myocardial infraction. As conceded in the Office Action, Miyata, et al. does not disclose or suggest the use of a phenyl-modified silicone elastomer or a fluoro-modified silicone elastomer. Joh, et al., on the other hand, discloses a polymer emulsion that may contain a polydiorganosiloxane capable of giving a thromboresistant surface.

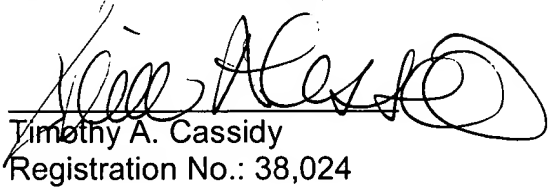
As opposed to the currently pending claims, however, neither reference discloses or suggests a gastrostomy feeding device as currently required in all of the pending claims. In particular, neither reference discloses or suggests a gastrostomy feeding device that includes an elongated feeding tube having a first end for insertion through a patient's abdominal wall and a second end that includes a feeding inlet. Instead, for instance, Miyata, et al. is directed to intraaortic balloon catheters. As a consequence, Miyata, et al. alone or in combination with Joh, et al. fails to disclose or suggest forming a retaining member of a gastrostomy feeding device out of a material comprising a phenyl-modified silicone or a fluoro-modified silicone. As such, it is believed that the claims patentably define over both of the above cited references.

It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Lam is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,

DORITY & MANNING, P.A.



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